herewith is a Supplemental Information Disclosure Statement as well as a Request for Continued Examination and the requisite fee. Please enter the following remarks into the record.

REMARKS

Claims 1-5 and 12 are pending in the instant application. Claims 1-5 and 12 have been rejected under 35 U.S.C. § 112, first paragraph. Reconsideration is respectfully requested in light of the following remarks.

I. Supplemental Information Disclosure Statement

Applicants are filing a Supplemental Information Disclosure Statement to bring to the attention of the United States Patent and Trademark Office prior art references identified by the European Patent Examiner in a corresponding European patent application. Applicants are filing a Request for Continued Examination and the requisite fee herewith so that due consideration can be given to these references and the Supplemental Information Disclosure Statement can be entered into the record of this case.

II. Submission of Declaration by Dr. Roberto Macina

On July 22, 2002, Applicants submitted a Rule 132 Declaration by Dr. Nam Kim. Since submission, it was found that

because of a sampling mix-up, data provided with Dr. Nam's Declaration may not have been representative of the Lng108 diagnostic marker. Accordingly, data provided with Dr. Kim's Declaration must not be relied upon for withdrawal of the enablement rejection under 35 U.S.C. § 112, first paragraph.

Instead, applicants are submitting a new Declaration by co-inventor Dr. Roberto Macina providing data demonstrative of the functional efficacy of Lng108 as a diagnostic marker for cancer. It is respectfully requested that Dr. Macina's Declaration and data provided therewith be relied upon for withdrawal of the enablement rejection under 35 U.S.C. § 112, first paragraph and, if possible, that Dr. Kim's Declaration be removed from the record of this case. Applicants are filing with this response a Request for Continued Examination and the requisite fee so that due consideration by the Examiner can be given to Dr. Macina's Declaration.

Dr. Roberto Macina's Declaration provides confirming data generated in accordance with teachings of the specification demonstrating that Lng108 is a unique cancer marker. Specifically, Dr. Macina's Declaration provides data from experiments measuring relative levels of Lng108, in cancerous, normal adjacent and normal tissue via quantitative PCR (See

paragraphs 5 and 6 of Dr. Macina's Declaration). Procedures for quantitative PCR are described in detail in the instant specification at page 20, line 16, through page 21, line 13 (also see paragraph 5 of Dr. Macina's Declaration). As shown in the graph attached to Dr. Macina's Declaration, also summarized in paragraph 6 of Dr. Macina's Declaration, levels of Lng108 are higher in cancer samples when compared to normal tissue and normal adjacent tissue for lung cancer. Further, as discussed in paragraph 7 of Dr. Macina's Declaration, the sensitivity of Lng108 for lung cancer is at least as high as other markers currently approved and used for diagnosis of various cancers. Accordingly, these data, generated in accordance with teachings provided in the instant specification, provide additional supporting evidence that Lng108 is useful as a unique cancer marker.

Further, as discussed in paragraph 9 of Dr. Macina's Declaration, the overexpression of Lng108 mRNA in cancer shown by these data is expected to correlate with protein expression as well.

Since the executed version of Dr. Macina's Declaration is a facsimile copy, Applicants are also providing a clearer courtesy copy of the expression graph attached to the Declaration.

Consideration of Dr. Macina's Declaration and maintaining the determination that the claimed invention is enabled under 35 U.S.C. § 112, first paragraph, is respectfully requested.

III. Rejection of Claims 1-5 and 12 under 35 U.S.C. § 112, first paragraph

Claims 1-5 and 12 have been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, has possession of the claimed invention.

Specifically, the Examiner suggests that recitation of "stringent conditions" without definition of what constitutes the physical conditions of stringent hybridization does not serve to limit the structure of the hybridizing polynucleotide. Further, the Examiner suggests that the instant Claims encompass allelic sequences, splice variants and homologs which are not fully described by the specification and which are not limited by a common structural or defined function.

Applicants respectfully traverse this rejection.

At the outset, Applicants respectfully disagree with the Examiner's suggestion that the polynucleotides encompassed by the

Claims are not limited to a common structural or defined function. Contrary to the Examiner's suggestion, the polynucleotides determined in the claimed methods of the present invention either comprise SEQ ID NO:1 or 2, hybridize under stringent condition to an antisense sequence of SEQ ID NO:1 or 2, or express the same protein as a polynucleotide of SEQ ID NO:1 or 2. The ability to hybridize under stringent conditions to an antisense sequence of SEQ ID NO:1 or 2, or the ability to express the same protein are clearly both structural and functional limitations supportive of the genus claimed. In fact, both the case law and MPEP are quite clear; in the molecular biology arts, if an applicant discloses an amino acid sequence, it is unnecessary to provide an explicit disclosure of all the nucleic acid sequences that encode the amino acid sequence. Since the genetic code is widely known, it has been deemed that the disclosure of an amino acid sequence provides sufficient information such that one would accept that an applicant was in possession of the full genus of nucleic acids encoding a given amino acid sequence. MPEP § 2163 and In re Bell, 991 F.2d 781, 785, 26 USPQ2d 1529 1532 (Fed. Cir. 1993) and In re Baird, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994).

SEQ ID NO:3 taught the instant application provides a polypeptide sequence encoded by SEQ ID NO:1 and 2. Thus, in accordance with established case law and MPEP §2163, the written description of this specification clearly allow persons of ordinary skill in the art to recognize that he or she invented SEQ ID NO:1 and 2 as well as the genus of polynucleotides expressing the same protein.

Similarly, methods for assessing whether a polynucleotide hybridizes under stringent conditions are widely known in the art of molecular biology. MPEP § 2163 explicitly states that "[w]hat is conventional or well known in the art need not be disclosed in detail". Also see Hybritech Inc. v. Monoclonal Antibodies, Inc. 802 F.2d at 1384, 231 USPQ at 94. MPEP § 2163 further states that "[i]f a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claimed is not explicitly described in the specification, then the adequate written description requirement is met." As made clear in paragraph 8 of Dr. Macina's Declaration, methods for assessing whether a polynucleotide hybridizes under stringent conditions to a known sequence, such as taught in the instant application, are taught in standard reference texts such as Sambrook et al. 1989

(molecular Cloning, A Laboratory Manual, 2nd Edition, Cold Spring Harbor Press, Cold Spring Harbor and such sequences can be identified routinely by those skilled in the art. Accordingly, further explicit disclosure of nucleic acid sequences that hybridize to SEQ ID NO:1 or 2 is not required to satisfy the written description requirement of 35 U.S.C. § 112, first paragraph.

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph is therefore respectfully requested.

IV. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending Claims is earnestly solicited.

Respectfully submitted,

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